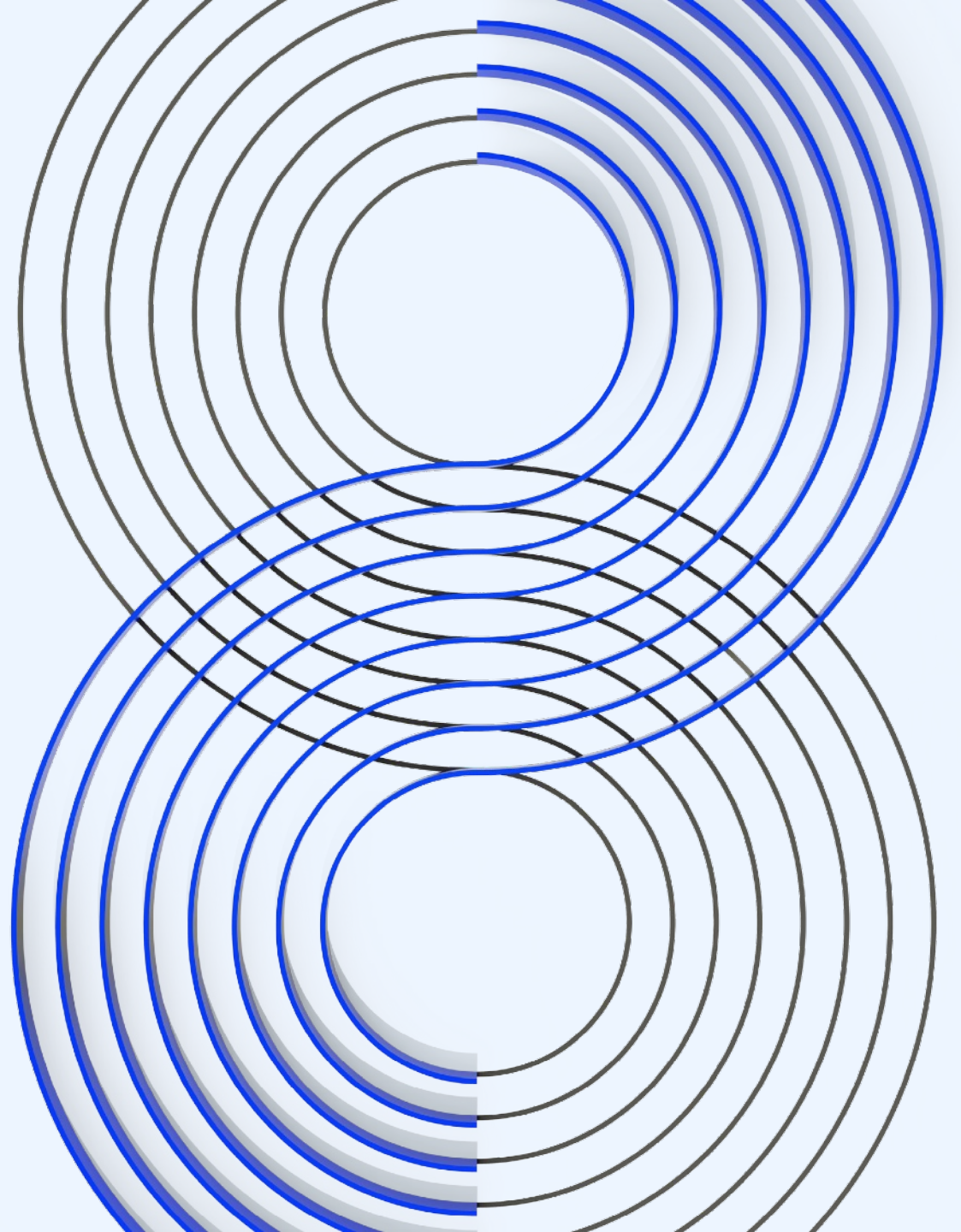


Exploring Potential Use of Generative AI in Regulatory Review



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What is Generative AI?

- Generative AI (GenAI) is a type of AI that can generate new, original content, such as text, images, music, and videos.
- GenAI applications offer a versatile range of functionalities, including:
 - Semantic Search with Question and Answer capability
 - Summarization
 - Content Creation
 - Code Creation and Conversion



What are GenAI's benefits to FDA?

- Streamline operations, improve productivity and foster resource optimization
- Enhance customer/citizen experience
- Scale employee expertise
- Expand organizational capabilities and improve decision-making
- Accelerate digital transformation agenda at FDA



What are GenAI's critical limitations for FDA?

- Pre-training approach for most LLMs remains consistent: sampling text from the pre-training corpus and training the model to predict the next word or token accurately.
- Given FDA's regulatory responsibilities, these models have known limitations that are critical for FDA to address during their adoption:
 - Generating plausible but incorrect information, i.e., hallucination
 - Limitation in its ability to carry out symbolic, mathematical, and algorithmic reasoning tasks
 - Lack of domain knowledge
 - Lack of up-to-date information

Techniques to Address GenAI's Limitations

- Retrieval Augmented Generation (RAG)

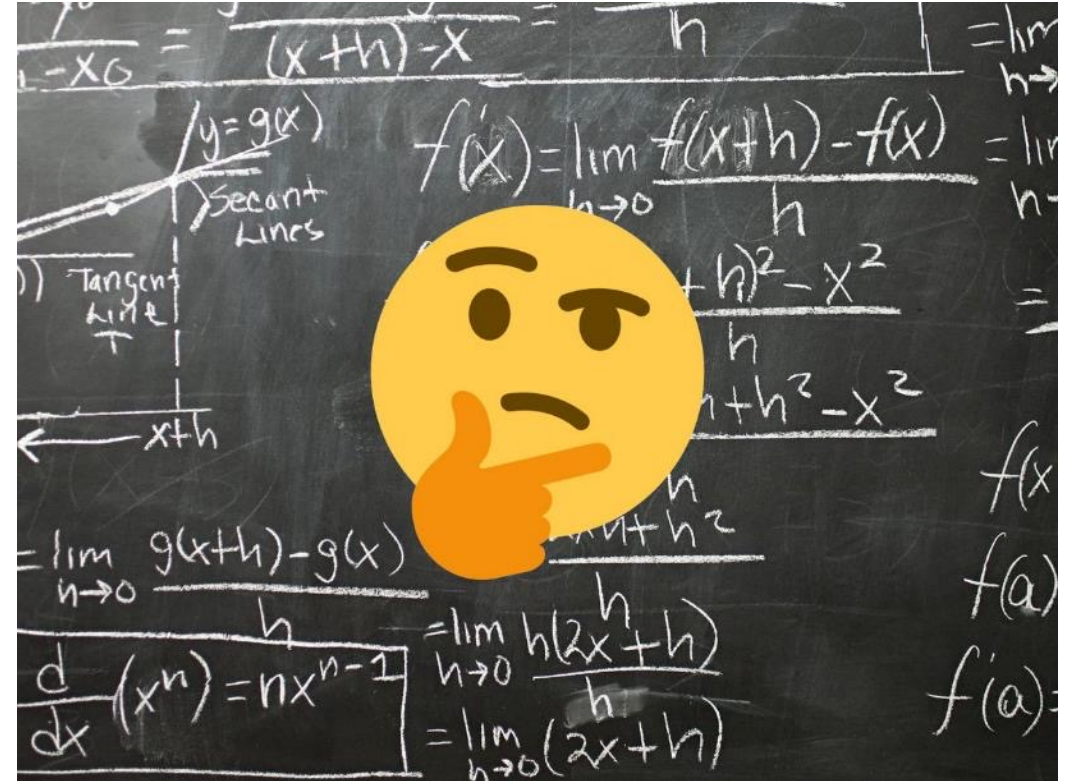
- RAG is an AI framework for retrieving facts from an external knowledge base and then having GenAI generate contents based on these facts.
- RAG can effectively address several challenges faced by generative AI through a combined approach of content generation and retrieval:
 - Reduced Hallucination and Improved trustworthiness
 - Domain-specific information
 - Up-to-date information
 - Cost-effectiveness



Techniques to Address GenAI's Limitations

- Program-aided Language Models (PAL)

- PAL is a framework designed to address GenAI's limitation with symbolic, mathematical, and algorithmic reasoning tasks.
- It uses GenAI to read natural language problems and generate programming code as reasoning steps. The code is then executed by an interpreter to produce the answer.
- This approach is massively beneficial to the accuracy and reliability of GenAI in solving reasoning-based tasks.



Techniques to Address GenAI's Limitations

- Reinforcement Learning from Human Feedback (RLHF)

- RLHF uses reinforcement learning (RL) to finetune the LLMs with human feedback data.
- It results in a model that is better aligned with human preferences, e.g.,
 - Minimizing the potential for harm including giving caveats that acknowledge limitations and avoiding toxic language and topics, or
 - Maximizing usefulness and relevance to the input prompt.



Potential Utilization of GenAI in Regulatory Review Process at FDA



- While GenAI can be applied to transform the regulatory review process, it is only complementary to human expertise and not a replacement.
- FDA shall continue to evaluate and incorporate advanced technologies responsibly into its workflow.

Potential Utilization of GenAI in Regulatory Review Process at FDA

- Sample Use Cases



- Monitor social media platforms for discussions, concerns, and trends related to FDA-regulated products, flagging potential misinformation
- Create drafts for press releases, public announcements, and updates based on specified source documents or key points
- Respond to queries from the public and industry
- Assist in generating content for educational materials.

Potential Utilization of GenAI in Regulatory Review Process at FDA

- Sample Use Cases



- Answer queries, provide guidance on regulatory pathways, and assist in the preparation of regulatory submissions by retrieving relevant information from regulatory documents, guidance manuals, and other relevant resources published by FDA

Potential Utilization of GenAI in Regulatory Review Process at FDA

- Sample Use Cases



- Document Management during Drug Application Review
- Standard Tables and Figures Generation
- Code Generation / Code Conversion
- Knowledge Management
- Drafting Information Requests and Other Artifacts

Potential Utilization of GenAI in Regulatory Review Process at FDA

- Sample Use Cases



- Analyze diverse data sources, including electronic health records (EHRs), social media, and healthcare databases, to automatically detect and flag potential adverse events

Potential Utilization of GenAI in Regulatory Review Process at FDA

- Sample Use Cases



- Automate the review of documents, such as batch records, standard operating procedures (SOPs), and quality control documents, against the GMP standards
- Quickly identify discrepancies or non-compliance issues within large sets of documents

Potential Utilization of GenAI in Regulatory Review Process at FDA

- Sample Use Cases

Communication with Public

Guidance and Assistance to Industry

Pre-market Approval

Post-market Surveillance

Inspections and Compliance Enforcement

Internal Operations 

- Draft job postings based on historical postings
- Screen resumes by extracting key credentials and rank the candidates based on preset criteria
- Help plan for meetings by analyzing agendas and minutes from past meetings
- Assist in developing training materials and resources
- Answer staff's questions based on available training materials

Effectively harness the benefits of GenAI while ensuring its deployment aligns with ethical, legal, and societal values

Safe AI EO & OMB Draft Policy

- On Oct. 30th, 2023, President Biden signed a groundbreaking Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence
- The Office of Management and Budget (OMB) has introduced a draft policy - Advancing Governance, Innovation, and Risk Management for Agency Use of AI

Strategies for Fully Leveraging the Potential of GenAI

- Identify the proper use cases to start their GenAI adoption
- Invest in data preparation and management
- Establish a multidisciplinary team
- Develop and follow ethical guidelines
- Continuously evaluate the performance of GenAI systems and make adjustments as needed

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